DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3741. Misbranding of RecTone devices. U. S. v. 9 Cartons, etc. (F. D. C. No. 32156. Sample No. 16377–L.)

LIBEL FILED: November 29, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about June 6 and October 4 and 16, 1951, by the Walker-Young Corp., from Long Beach, Calif.

PRODUCT: *RecTone devices.* 9 cartons, each carton containing 1 rubber bulb air pump with hose and 10 RecTone medicators, with some of the cartons containing a leaflet printed in blue ink and other cartons containing a leaflet printed in black ink, both entitled "RecTone The Method of Humane Rectal Therapy," and one carton containing a leaflet entitled "Reference Manual," at Kansas City, Mo. In addition to the 9 cartons, there were 3 cartons, each containing 10 RecTone medicators and one of the leaflets entitled "RecTone * * *" in blue or black ink, also at Kansas City, Mo.

Each RecTone medicator was inclosed in a cellophane envelope and consisted of a cylindrical, elastic, finger-like bag closed at one end and having an open tube at the other for attaching to the air pump. The medicators were approximately 5 inches long and between ½ inch and ¾ inch in maximum diameter.

LABEL, IN PART: (Cellophane envelope) "RecTone Medicator The Medicament Herein Contains: Benzocain 4% Phenol 0.5% Boric Acid, Bismuth Subnitrate, Resorcin 0.5% Balsam Peru, Zinc Oxide and Aquaphor Water Soluble Base."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used as suggested in its labeling, namely, by inserting into the rectum and inflating.

Further misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the above-mentioned leaflets, were false and misleading. The statements represented and suggested that the article was an effective treatment for piles; for restoring rectal health and a sense of well-being to the individual; for hemorrhoids; for bleeding, itching, or burning conditions of the anal canal; for stricture of the anal canal; for destroying infection and reviving fresh blood circulation in the strangulated hemorrhoidal vein system, thus enabling the natural healing powers of the blood to operate in releasing nerve tension and mending ailing tissue; for chronic conditions of the anal tract; for retoning rectal nerves and muscles; for enabling the all-important sphincter muscles to become pliable and strong and resume their normal function; and for controlling scar tissue and speeding up the healing process following surgery. The article was not an effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: January 22, 1952. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.